IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	**Confirmation No. 5291**
Mie TAKAHASHI et al.	:	Attorney Docket No. 2001_1464A
Serial No. 09/937,730	:	Group Art Unit 1641
Filed January 8, 2002	:	Examiner Gary W. Counts
CHROMATOGRAPHY MEDIUM AND ITS MANUFACTURING METHOD	:	**Mail Stop: AMENDMENT**

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Mie Takahashi, the undersigned, a citizen of Japan, residing at 1891-1 Minamigata, Toon-shi, Ehime 791-0301, Japan, do hereby declare:

1. That I am a co-inventor of the above-identified application.

2. That I graduated from Yamaguchi university in March, 1994 with a degree in Agriculture, specializing in Bioscience, Biotechnology and Agrochemistry.

3. That I have been working at Panasonic Shikoku Electronics Co., Ltd. for 14 years.

4. (Relevant Publications, awards, or other distinguishing professional recognizations)
None

5. That in order to show the novelty and unobviousness of the invention of the above-identified application, I have under my control and direction conducted the following experiments.

The particulars and results of the experiments are set forth below.

EXPERIMENTAL

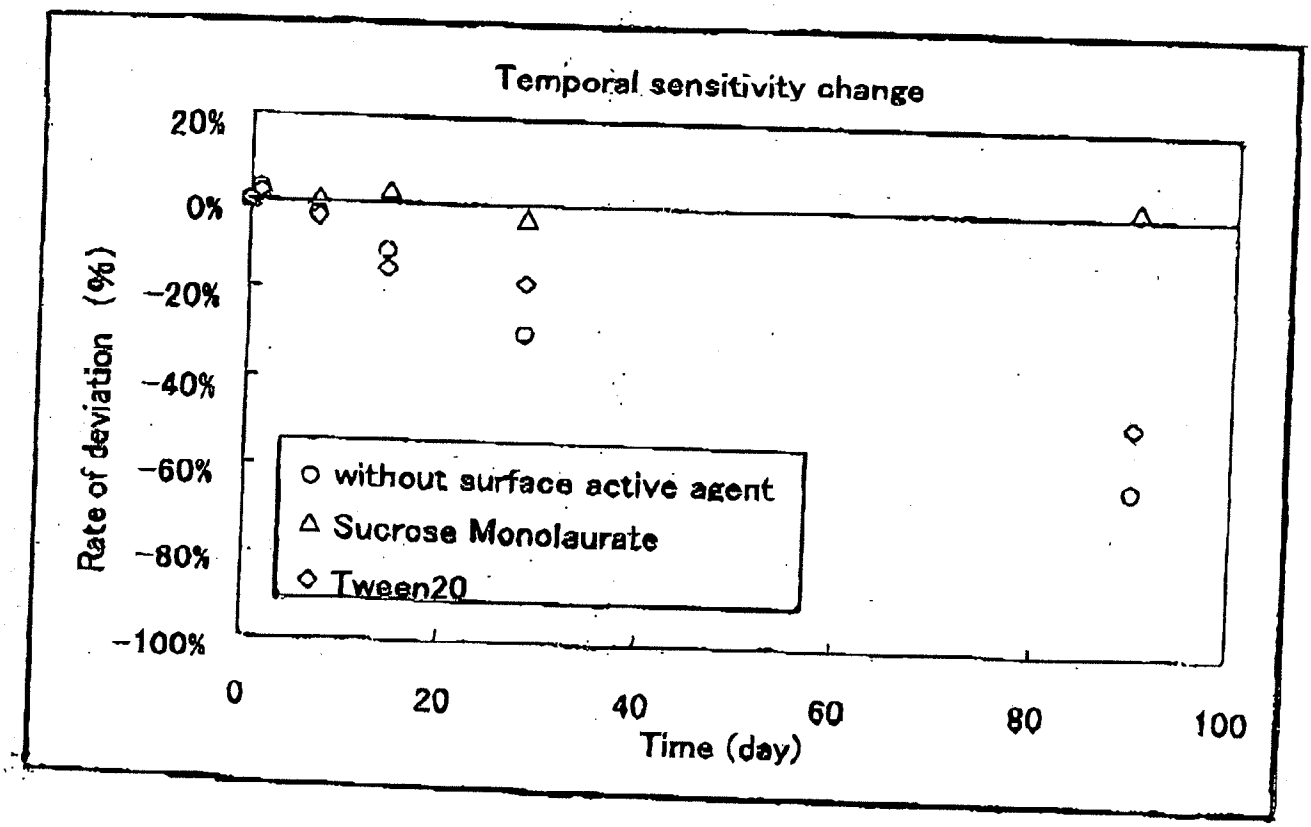
A chromatography specimen was produced in accordance with Example 1 of Applicants' specification. Specifically, in accordance with Example 1 (pages 33-34) of Applicants' specification, an anti-hCG-β antibody solution, obtained by dilution with a phosphate buffer solution to perform the concentration adjustment, was produced for an immunochromatography specimen. This antibody solution was applied on the nitrocellulose film by adopting a solution discharge device. Thereby, an antibody immobilization line for detection was obtained on the nitrocellulose film. After the nitrocellulose film was dried, this nitrocellulose film was immersed in a Tris-HC1 buffer solution including 1% skim milk and gently shaken for 30 minutes. After 30 minutes, the nitrocellulose film was moved into a Tris-HC1 buffer solution tank, gently shaken for 10 minutes, and then gently shaken in another Tris-HC1 buffer solution tank for another 10 minutes, so as to wash the nitrocellulose film. After washing twice, the nitrocellulose film was immersed in a Tris-HC1 buffer solution including 0.05% Sucrose Monolaurate (made by Dojindo Laboratories), shaken for 10 minutes, then taken out from the solution tank, and dried at room temperature.

Another test specimen was similarly produced, except that Tween20 (Polyoxyethylene Sorbitan Monolaurate) was used instead of 0.05% Sucrose Monolaurate. [This specimen is based upon a surfactant taught by the Chu reference.]

The test specimens were then stored in an aluminum seal, which also includes a molecular sieve as a desiccant, in a reservoir with a constant temperature of 25°C. After l day, 7 days, 14 days, 28 days, and 90 days of storage, a measurement for each specimen was performed by applying blood plasma including hCG of 0, 100, 1000, and 10000U/l (which were adjusted for each specimen) to the test specimens, as in the Examples of the Applicants' specification. By setting the sensitivity at the time of setting a regression formula as 0, the total concentration mean of the change in sensitivity from the beginning is plotted on a graph, shown below.

RESULTS

The graph compares the test specimen treated with 0.05% Sucrose Monolaurate, the test specimen which was treated with 0.05% Tween20 in place of the 0.05% Sucrose Monolaurate, and a test specimen where no treatment is performed with surface active agent.



As shown in the above graph, the test specimen which was not treated with a surface active agent provides sensitivity which begins to gradually decrease on the 7th day, and has a sensitivity reduction of up to about 60% on the 90th day. Additionally, the test specimen treated with Tween20, which does not comprise sugar structure in a hydrophilic part and is surface active agent in liquid form at normal temperature and normal pressure, similarly indicates a decrease in sensitivity, i.e., about -4%, on the 7th day. Further, the test specimen treated with Tween 20 has a sensitivity

reduction of about -50% on the 90th day. On the contrary, the test specimen in accordance with Applicants' claims does not have a decrease in sensitivity. The poor results of the other two specimens arise from multiple factors, such as a debasement of permeability caused by the test specimen structure in this technical field using the permeability of test body, alteration and deactivation of specific protein caused by the mixing of liquid materials, and an increase in the background caused by the labeled-substance nonspecific adsorption which results from the above-mentioned matters.

I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Date: Dec 11, 2008

Mie Takahashi

(Signature of Declarant)